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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,359	03/16/2001	Tacyoung Yoon	49662 [72021]	7721
21874	7590	12/09/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,359

Applicant(s)

YOON ET AL.

Examiner

Tamthom N. Truong

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22,24-27,30,35,39-64 and 67 is/are pending in the application.
- 4a) Of the above claim(s) 18-22,39-64 and 67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1,3,5-12,24-27,30 and 35 is/are rejected.
- 7) ☒ Claim(s) 4,13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

Applicant's amendment of 09-16-05 has been fully considered. The deletion of –C(=O)O- and –CH₂- from the definition of X, and the deletion of alkynyl and –O-(C₂₋₆alkynyl) has overcome the previous rejections of 102 for claims 3, 5 and 6. Said deletion has also overcome the previous rejection of 103 for claims 1, 3-5, 7, 9, 10 and 14 based on Minn et. al. (WO'159). Therefore, the previous 102 and 103 rejections are withdrawn herein. The deletion of variable Z in claim 3 has overcome the 112/2nd paragraph rejection for claims 3-8 as well.

Claim 30 was inadvertently included in the 112/2nd paragraph rejection.

However, applicant's argument has not overcome the previous 112/2nd paragraph rejection for claim 27.

Claims 2, 23, 28, 29, 31-34, 36-38, 65, 66 and 68 have been cancelled.

Claims 18-22, 39-64 and 67 are withdrawn.

Claims 1, 3-17, 24-27, 30 and 35 remain for consideration.

The scopes of claims 1, 3, 9, 10, 15 and 17 have been changed which raise the following new ground(s) of rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites the broad limitation of “*a stress-related disorder*”, followed by the narrow limitation of “*an anxiety disorder*”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).
2. Claim 27 also recites the limitation of “an eating disorder” which includes disorders with opposite symptoms such as: bulimia, anorexia, and obesity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 24-26, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kim et. al.** (US 3,517,007). For example, the compound of claim 7 on column 8 of US'007 reads on the pyrimidine formula recited in claim 1 with the following substituents:

- i. One of R_1 and R_3 is monoalkylcarboxamide, which can be substituted with a C_{1-6} alkoxy; the other is hydrogen;
- ii. R_2 is monoalkylcarboxamide;
- iii. Ar is a substituted phenyl group.

Claims 24-26 recite compounds with IC_{50} values. Although the reference does not reveal said values, they represent biological activity that would have been inherent in the structure of the compounds. Since claims 24-26 do not indicate specific compounds with specific values, it is presumed that any compound (of claim 1) would have the IC_{50} values recited, and thus, would be inherently anticipated by the compound of Kim et. al.

Claim 30 recites a compound with activity of *in-vitro* Na channel functional assay, which would be inherent in the structure of compounds recited in claim 1, and thus, would also be inherently anticipated by the compound of Kim et. al.

Claim 35 recites a pharmaceutical composition which is taught on lines 39-58 of column 3 in US'007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 5-8 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hepworth et. al.** (US 3,592,895). On column 21, Hepworth et. al. disclose a compound of *N*- β -diethylaminoethyl-(2-*p*-chlorobenzyl-6-methoxypyrimid-5-yl)acetamide, which is analogous to a compound of the pyrimidine formula recited in claims 3, and 5-8 having the following substituents:

- iv. One of R₁ and R₃ is alkoxy while the other is hydrogen;
- v. R₂ is -NHC(=O)R_A; R_A is an alkyl group;
- vi. Ar is a substituted phenyl group.

Said compound is also analogous to those recited in the instant claims 9-12 when the pyrimidine formula has the following substituents:

- vii. One of R₁ and R₃ is alkoxy while the other is hydrogen;
- viii. One of R_x and R_y is -C(=O)alkyl_A;
- ix. Ar is a substituted phenyl group.

The disclosed compound has anti-inflammatory, analgesic and anti-pyretic activity. However, it differs from the claimed compound by having the *benzyl* group at the 2nd position, and not a *phenyl* group as claimed herein. Such a difference can be overcome by the generic teaching on column 1. The disclosed *pyrimidine* genus has 4 variables with very narrow scopes. Of those variables, Y represents either *phenyl* or *benzyl* group. Thus, there is an equivalent teaching for *phenyl* and *benzyl* group. Furthermore, other species in US'895 also have *phenyl* group as a substituent at the 2nd position. Therefore, the skilled artisan would have been motivated to modify the cited compound by replacing the *benzyl* group with a *phenyl* group because such a modification would have still maintained the same biological activity.

Thus at the time that the invention was made, it would have been obvious to make the compounds recited in claims 3, 5-8 and 9-12 in view of the teaching above.

Claim Objections

5. Claims 4, 13, 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The above claims recites subgenera of pyrimidine formula in which the combination of substituents $-NR_xR_y$ at the 5th position, and Ar at the 2nd position of the pyrimidine ring that are not taught or fairly suggested by the prior arts of record.

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Allowable Subject Matter

6. Claims 15-17 are allowable because they recite pyrimidine compounds with the combinations of $-OR_x$ or $-NR_xR_y$ at the 5th position, and Ar at the 2nd position that are not taught or fairly suggested by the prior arts of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

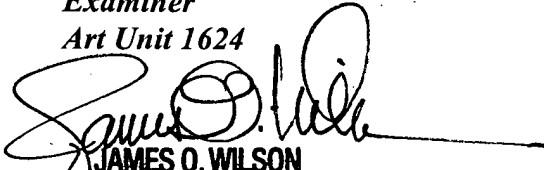
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11-18-05


Tamthom N. Truong
Examiner
Art Unit 1624


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